

**UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF TEXAS
SAN ANTONIO DIVISION**

WAVE NEUROSCIENCE, INC. a Delaware
Corporation,

Plaintiff,

vs.

BRAIN FREQUENCY LLC, a Texas Limited
Liability Company

Defendant.

Case No. 5:23-CV-00626-XR

Honorable: Xavier Rodriguez

PLAINTIFF'S REPLY IN SUPPORT OF OPENING CLAIM CONSTRUCTION BRIEF

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I. Introduction

Claim construction is an essential aspect of every patent infringement lawsuit. Consequently, the evidence presented in support of each party's proposed claim construction of the claim terms at issue must be consistent with the intrinsic evidence of the patents at issue and reflect applicable claim construction case law. So too, any opinions provided by a party's retained expert are only valuable and may only be considered from an expert qualified as a person of ordinary skill in the art ("POSITA") to which the patents at issue ("Asserted Patents") relate. In this instance, Defendant's evidence fails in almost every respect to align with the intrinsic evidence contained in the Asserted Patents and to comply with the requirements set forth in case law governing claim construction. In addition, Defendant's retained expert fails to meet even Defendant's own lower standard to qualify as a POSITA. Defendant's assertions as to invalidity also run afoul of the intrinsic evidence, established case law, and fail to meet the stringent legal standard necessary to prevail in invalidating any of the claim terms in dispute.

Conversely, Wave has gone to great lengths to provide abundant evidence from the written specification, figures, and claims contained within each of the Asserted Patents and, where appropriate, from the corresponding Prosecution History of the Asserted Patents to support its proposed constructions for each of the claim terms in dispute. In addition, Wave has retained an eminently qualified expert, (whose qualifications Defendant has not challenged, nor could it) to provide detailed expert declarations as to the technical reasons supporting Wave's proposed construction for each of the claim terms to be construed. Where appropriate, as further support of Wave's proposed constructions, relevant and reliable extrinsic has been provided to assist the Court.

A careful review of the evidence presented by Wave, including the intrinsic evidence from the Asserted Patents, the opinion of Wave's technical expert, and the further extrinsic evidence

provided by Wave, all reinforce that Wave's, not Defendant's, proposed constructions are the most appropriate for the Court to adopt in this case. Similarly, Defendant fails in its burden to meet the strict standard for holding a claim term invalid, precluding any such finding in this case.

II. Level of Ordinary Skill in the Art

While Defendant proposed its own definition of a POSITA in its opening claim construction brief (Dkt. 34 at *4), Defendant did not address, let alone dispute Wave's proposed definition for a person of ordinary skill in the art ("POSITA") in its response. Apparently Defendant finds no fault with Wave's proposed definition for a POSITA as a person with sufficient familiarity and experience with the subject matter of the Asserted Patents which could be obtained by: (i) successfully completing a Bachelor's degree in Electrical Engineering or Biomedical Engineering or similar discipline with classes or experience directed to electrophysiology and signal processing and TMS; (ii) a medical degree focusing on treatment of patients with brain disorders and experience with EEG and application of electrical or magnetic energy such as TMS; or (iii) at least three (3) years of experience in a job working with patients having brain disorders using treatment protocols involving TMS and EEG/electrophysiology. *See* Plaintiff's Opening Claim Construction Brief ("Wave's Op. Brief"), Dkt. 32 at *5-6; Bikson Op. Dec., Dkt. 32-5 ¶¶ 11-16.

In contrast, Wave and its technical expert, Dr. Marom Bikson, explained in its response to Defendant's Opening Claim Construction Brief ("Wave's Resp. Brief") why Defendant's proposed definition for a POSITA is insufficient. *See* Dkt. 38 at *1-3; Bikson Resp. Dec., Dkt. 38-2 ¶¶ 11-17. Specifically, Defendant first contends that a POSITA would be a person having a "graduate degree in mental health, neuroscience, or a related field with substantially similar courses, and 3-4 years of work experience". *See* Dkt. 34 at *4. However, as explained by Dr. Bikson, "[a]t their core, the underlying technology of the patents is related to electrophysiology

and signal processing which is then used by doctors and other medical practitioners to treat mental health disorders.” Bikson Resp. Dec. ¶ 14. These patents are engineering based and used in the context of treatment for mental health disorders. *Id.* A background and training in mental health will not provide the necessary background and understanding for the technology disclosed and claimed in these patents. Thus, a graduate degree in “mental health” and other “related field[s]” would not provide the training and education necessary to be a POSITA for the Asserted Patents. *Id.* ¶ 17.

Moreover, to date, despite filing both an opening and responsive claim construction brief, Defendant and its expert have failed to provide any explanation as to why its proposed education requirements would qualify a person as a POSITA for the Asserted Patents. “The importance of identifying the education and experience of one of skill in the art has long been established.” *Seoul Semiconductor Co. v. Nichia Corp.*, 596 F. Supp. 2d 1005, 1011 (E.D. Tex. 2009). This is not a situation where there is “no meaningful difference between the parties competing proposals”. *Polaris PowerLED Techs., LLC v. Samsung Elecs. Am., Inc.*, 2019 WL 121970, at *5 (E.D. Tex. Jan. 7, 2019). The Parties have proposed fundamentally different standards for a POSITA. However, Defendant has and continues to fail to support its proposed definition or dispute Wave’s.

This is not particularly surprising considering Defendant’s expert, Dr. Dempsey, does not even qualify as a POSITA under Defendant’s own proposed definition. Defendant and Dr. Dempsey also proposed that a POSITA would have “advanced training and experience in use of either EEG or TMS technology”. Dkt. 34 at *4. As fully detailed in Wave’s Motion to Strike Dr. Dempsey (Dkt. 39), Defendant failed to show that Dr. Dempsey¹ has the “advanced training and

¹ As further detailed in Wave’s Motion to Strike, Dr. Dempsey’s declaration is also conclusory and unsupported and Dr. Dempsey himself is biased towards Defendant. *See* Dkt. 39 at *8-13.

experience” in either EEG or TMS technology, despite receiving multiple attempts to do so. *See also* Bikson Reply Dec. ¶¶ 8-12.

In any case, even if Dr. Dempsey qualified as a POSITA under his own definition, training in either EEG *or* TMS is not sufficient. TMS technology is central to the Asserted Patents. *See also* Bikson Resp. Dec. ¶ 15. Importantly, training and experience in “EEG” technology would not qualify a POSITA to opine regarding the ’111 Patent, which is specifically directed to “non-EEG biological metrics”. *See* Dkt. 029-2, ’111 Patent, at 7:57-58; Bikson Resp. Dec. ¶ 16. Thus, experience and training in EEG technology is similarly insufficient to qualify as a POSITA for the Asserted Patents.

It is undisputed that Dr. Dempsey does not have the type of engineering background necessary for a POSITA in this case. *See* Dkt. 34-1 ¶ 4 (stating that Dr. Dempsey has “a Doctor of Philosophy in Clinical Psychology with a specialty in neuroscience”). Since Wave’s proposed definition of a POSITA stands un rebutted and in light of Defendant’s failure to provide any support or argument as to why its proposed POSITA definition is correct, the Court should adopt Wave’s proposed definition of a POSITA and disregard and/or strike Defendant’s expert’s declaration since Dr. Dempsey is not a POSITA.

III. Claim Terms in Dispute

A. “Intrinsic Frequency”

No.	Claim Term/Phrase and Asserted Claims Containing Term	Plaintiff’s Proposed Construction and Supporting Intrinsic Evidence	Defendant’s Proposed Construction and Supporting Intrinsic Evidence
14	Intrinsic frequency ’490 Patent, Claim 1 ’408 Patent, Claims 1-2, 12, 20 ’111 Patent, Claims 3, 7 ’737 Patent, Claims 1-2, 4	frequency selected to which treatment is to be applied	the frequency (f0) at which peak signal power in the specified band (Emax) is located

No.	Claim Term/Phrase and Asserted Claims Containing Term	Plaintiff's Proposed Construction and Supporting Intrinsic Evidence	Defendant's Proposed Construction and Supporting Intrinsic Evidence
			For '111 Patent: Indefinite & Invalid: Not enabled/ lacking written description

Defendant makes six arguments in response to Wave's proposed construction of "intrinsic frequency" as "frequency selected to which treatment is to be applied". All of Defendant's arguments fail.

Defendant's first and third arguments substantially overlap. In sum, Defendant asserts that "intrinsic frequency" is not defined or explained in either Wave's proposed construction or in the intrinsic evidence and is not known in the art. Dkt. 37 at *1-3. Defendant also claims that neither Wave's proposed construction nor the intrinsic frequency explain *how* to move such an intrinsic frequency once defined. *Id.* at *1. Defendant is wrong on both accounts.

Tellingly, Defendant provides no evidence in support from its expert or any other source explaining how or why a POSITA would not understand what an intrinsic frequency is or how one is measured. In contrast, Wave's expert, Dr. Bikson, explained extensively in both his opening and responsive claim construction declarations that (1) "intrinsic frequency" is a term of art understood by a POSITA, (2) that the specification provides evidence of what the "intrinsic frequency" is, and (3) that "intrinsic frequency" was commonly used and understood in the industry as of, at least, the priority dates of the Asserted Patents. *See* Dkt. 32-5 (Bikson Op. Dec.) ¶ 61 (Dr. Bikson explaining that each "subject has their own internal, i.e. intrinsic, frequency which can be measured by an EEG"), ¶ 63 (explaining that the '408 Patent, for example discloses influencing the intrinsic frequency of the brain using a magnetic field), ¶ 76 (explaining that brain has an intrinsic frequency as described in the '111 Patent), ¶ 80 (explaining that the '408 Patent was amended to describe

specific ranges of measurements for the intrinsic frequency); Dkt. 38-2 (Bikson Resp. Dec.) ¶ 42 (explaining that the patent examiner understood “intrinsic frequency” during prosecution of the ’408 Patent as a measured brain wave of a subject (similar excerpts from the other Asserted Patents in surrounding paragraphs), ¶ 46 (Dr. Bikson explaining that “intrinsic frequency” and “TMS” were “commonly used and well-known in the art”), ¶ 49 (Dr. Bikson detailing that “intrinsic frequency” was used in conjunction in the art for many years before the priority dates for the Asserted Patents), ¶ 56 (Dr. Bikson explaining that “intrinsic frequency” is a term of art and has an ordinary meaning).

Since “intrinsic frequency” is a term of art known to a POSITA, an express definition in the specification is *not* required. *See Niazi Licensing Corporation v. St. Jude Medical S.C., Inc.*, 30 F.4th 1339, 1347 (Fed. Cir. 2022); *K-fee System GmbH v. Nespresso USA, Inc.*, 89 F.4th 915, 923 (Fed. Cir. 2023); *Janssen Pharmaceutica, N.V. v. Mylan Pharmaceuticals, Inc.*, 2017 WL 66342, at *2 (D. Del. Jan. 6, 2017). Any argument that Wave was required to expressly define “intrinsic frequency” in the intrinsic evidence, thus, fails.

Importantly, Defendant describes its proposed construction as an “expressed definition” found in the specification of the Common Asserted Patents. Dkt. 37 at *3. As fully detailed in Wave’s Responsive Claim Construction Brief, Defendant’s proposed construction is **not** directly lifted from the Common Asserted Specifications. *See* Dkt. 38 at *10. Instead, it is cobbled together from multiple disclosures in the patents to design a self-serving construction for Defendants. *Id.* Given that Defendant’s proposed construction is not as represented and, as detailed below, is directed not to “intrinsic frequency”, but to “Q-factor” (*infra* at *9), the proposed construction should not be adopted.

Defendant also argues that even if an “intrinsic frequency” is known, the Asserted Patents fail to explain how any movement of that intrinsic frequency is measured. Dkt. 37 at *1. Yet Defendant simultaneously admits that “common sense” dictates measuring an intrinsic frequency both “before and after treatment”. *Id.* Defendant even quotes Dr. Bikson explaining that everyone has an intrinsic frequency and that such an intrinsic frequency “can be measured by an EEG”. *Id.* (quoting Bikson Op. Dec. ¶ 61).

For clarity, movement of an “intrinsic frequency” can be measured by an EEG both before and after treatment. The Asserted Patents explain this. *See* Dkt. 32-5 ¶¶ 65-67 (disclosures from the ’408 Patent discussing “a sample EEG segment for a subject before therapy is delivered” and an “EEG ... sampled immediately following therapy”). And a POSITA would understand how to measure the subject’s intrinsic frequency. *Id.* ¶ 77; Dkt. 38-2 ¶¶ 40, 46, 50.

Defendant’s second argument is two-fold. First, Defendant asserts that Wave of “improperly reads [out] the qualifier ‘intrinsic’ out of the claim language.” Dkt. 37 at *2. Nothing could be further from the truth. Dr. Bikson explained that each “subject has their own **internal, i.e. intrinsic**, frequency that can be measured by an EEG.” Dkt. 32-5 ¶ 61. An EEG measures brain waves. Wave does not dispute these statements or concepts and is not attempting to broaden its construction to “any frequency selected to which treatment is applied” (such as a non-brain frequency) as Defendant claims. Dkt. 37 at *2 (emphasis removed).²

Next, Defendant erroneously claims that Wave’s proposed construction for “intrinsic frequency” is inconsistent with the phrase “pre-selected intrinsic frequency” as used within the asserted claims. As detailed in full in Wave’s Responsive Claim Construction Brief (Dkt. 38 at *10-11), Defendant agreed to a construction for “pre-selected intrinsic frequency” as “a targeted

² If Defendant’s argument had any merit, it would apply equally to Defendant’s construction that does not include the word “intrinsic”.

intrinsic frequency chosen before treatment”. Dkt. 31 at *5. The claims require both: (i) an intrinsic frequency that is being treated or moved in the claims; and (ii) a pre-selected or target intrinsic frequency that is the goal frequency (i.e. the frequency the treatment is attempting to move the subject’s intrinsic frequency to or toward). Dkt. 38 at *10-11. When properly addressed, there is no confusion as to these two claim terms as Defendant asserts.

Defendant’s fourth, fifth, and sixth arguments also overlap and suffer from similar faults. First, in all three arguments, Defendant, improperly, attempts to import limitations from specific embodiments disclosed within the specification. *See* Dkt. 37 at *3-5 (arguments 4 and 6 discussing Figure 12 and argument 5 references Figures 5-6). In fact, Defendant admits that its proposed construction is based on importing limitations from a specific embodiment disclosed within the specification. *See* Dkt. 37 at *3. The law is clear that this is improper absent an express intention by the Applicant to do so. *See CollegeNet, Inc. v. ApplyYourself, Inc.*, 418 F.3d 1225, 1231 (Fed. Cir. 2005); *Liebel- Flarsheim Co. v. Medrad, Inc.*, 358 F.3d 898, 906 (Fed. Cir. 2004). Despite multiple opportunities to do so, Defendant has *never* identified where Wave expressed an intent to import a limitation from an embodiment into the claims. Nor can it.

While there is more than one embodiment of “intrinsic frequency” disclosed in the specifications, even if Defendant *was* correct that there was only a single embodiment of “intrinsic frequency” disclosed, that is not a sufficient reason to incorporate a specific embodiment into a construction absent express intention on the part of the Applicant (here, Wave). *See Liebel- Flarsheim*, 358 F.3d at 906 (explaining that the Federal Circuit “has expressly rejected the contention that if a patent describes only a single embodiment, the claims of the patent must be construed as being limited to that embodiment”). In any case, Defendant clearly understands that

there are multiple embodiments related to “intrinsic frequency”. As explained above, Defendant’s own construction is a hybrid of disclosures regarding Figures 6 and 12. *See supra* at *6.

Defendant further accuses Wave of ignoring evidence in Figure 5 and 6 that allegedly supports Defendant’s proposed construction. *See* Dkt. 37 at *4-5. Again, Figures 5 and 6, while illustrative, are specific embodiments and Defendant has cited no support that Wave intended for any limitation in those embodiments to be imported into the claims.³

Arguments 4 and 6 also suffer from another issue: both arguments rely on Figure 12, a figure describing how to calculate the *Q-Factor*, not the intrinsic frequency. *See* Dkt. 37 at *3, *5. Tellingly, Defendant itself fails to distinguish or explain why a disclosure for *Q-Factor* should suffice to define “intrinsic frequency”. No matter how many times Defendant attempts to convince the Court otherwise, Figure 12 is directed to another concept (Q-Factor) and, at best, serves as an exemplary embodiment of one intrinsic frequency. Unsurprisingly, Defendant also entirely ignores Wave’s argument that Wave’s construction is easier to understand since it uses plain English. *See* Dkt. 32 at*16-17.

Defendant lastly argues that that Wave provides no supporting intrinsic evidence from the ’111 Patent and that the term is, thus, indefinite. Dkt. 37 at *6. This is incorrect. Wave provided such supporting evidence in both its opening and responsive claim construction briefs. *See* Dkt. 32 (Wave’s Opening Claim Construction Brief at *14) and Dkt. 38 (Wave’s Responsive Claim Construction Brief at *13), for example. And “intrinsic frequency” as used in the ’111 Patent is not indefinite for the reasons detailed in Wave’s Responsive Claim Construction Brief. Dkt. 38 at *13.

³ In any case, Figures 5 and 6 explain that the EEG recording is a “segment”, one which was simplified for the specification. *See* Dkt. 29-4 at 47:10-29. And nothing in these embodiments limits the measurement to only the peak power as Defendant claims. *Id.*

For all the above reasons, the Court should adopt Wave’s proposed construction and find that the “intrinsic frequency” as used in the ’111 Patent is definite.

B. “In-Phase” and “Out of Phase”

The terms “in-phase” and “out of phase” are used in Claims 1 and 12 of the ’408 Patent and Claim 1 of the ’490 Patent in relation to the concept of the EEG phase.

No.	Claim Term/Phrase and Asserted Claims Containing Term	Plaintiff’s Proposed Construction and Supporting Intrinsic Evidence	Defendant’s Proposed Construction and Supporting Intrinsic Evidence
14	In-phase/in phase ’408 Patent, Claims 1, 12 ’490 Patent, Claim 1	waveforms whose peaks and troughs occur at substantially the same time	waveforms whose peaks and troughs occur at the same time
16	Out of phase ’408 Patent, Claims 1, 12 ’490 Patent, Claim 1	waveforms whose peaks or troughs do not occur at substantially the same time	waveforms whose peaks or troughs do not occur at the same time

Defendant’s arguments regarding the related concepts of “in-phase” and “out of phase” suffer from a number of fundamental misunderstandings of the underlying art and technology. Importantly, Wave proposed construing the terms “in-phase” and “out of phase” to help the jury and Court since the terms are terms of art not commonly used by lay persons.

Indeed, Defendant’s first mistake arises from a misunderstanding Wave hopes to avoid with the jury. Colloquially, the terms “in” and “out” are opposites that may operate on a continuum. For example, a football player’s foot is “in” bounds until it is not at which point his foot is “out” of bounds. There is a clear line based on the rules of football that define when this transition occurs.

However, “in-phase” and “out of phase” in the context of EEG phase and the asserted patents do not exist on such a continuum. Bikson Reply Dec. ¶¶ 20, 23. Admittedly, Defendant does not use the word “continuum” in their responsive claim construction brief. However,

Defendant *does* fault Wave for not identifying the “point of demarcation” between “in phase” and “out of phase”. Specifically, Defendant argues that:

“Plaintiff’s proposal includes the term “substantially” for both terms, which *creates an overlap between the two concepts*. Under Plaintiff’s proposal, *it is unclear where that point of demarcation resides between “in-phase and “out-of-phase” – i.e., at what point would two magnetic fields be in-phase (peaks and troughs occur at substantially the same time) and out-of-phase (peaks and troughs do not occur at substantially the same time).*”

Defendant’s Opposition Claim Construction Brief, Page 6 (emphasis added). The primary (or perhaps only) reason a “point of demarcation” between in-phase and out of phase would be necessary is if the two concepts operate on such a continuum. They do not. Bikson Reply Dec. ¶¶ 31-32.

Instead, while related, the concepts are actually distinct features of signals that, in some circumstances, possibly can mirror each other. *Id.* ¶ 24. Both “in-phase” and “out of phase” are conventional terms in the scientific and engineering fields, commonly taught to undergraduate students early in their education. *Id.* ¶¶ 21-22. There are universally accepted approaches for identifying and measuring such signals and determining if they are “in-phase” or “out of phase”. *Id.* ¶¶ 25-28. A POSITA would not be confused as to how to identify or measure such signals. *Id.* ¶ 30. Tellingly, Defendant does not even attempt to provide any evidence to the contrary.

Pursuant to these well-understood and well-established scientific and engineering principles, evaluating whether or not two brain waves are “in phase” is a separate analysis from whether or not two brain waves are “out of phase”. *Id.* ¶¶ 24-28. Stated differently, if a POSITA is determining whether or not two brain waves are “in phase” and he or she comes to the conclusion that the two brain waves are *not* “in phase”, that does not mean that these same two brain waves

are, by definition, “out of phase.” *Id.* ¶¶ 27-28, 31. To determine if the two brain waves are “out of phase” requires a separate analysis. *Id.* It is possible that two brain waves are neither “in phase” nor “out of phase.” *Id.* ¶ 29.

Defendant’s arguments in favor of its proposed construction ignore these well-understood and long accepted scientific and engineering principals for determining whether or not two brain waves are “in phase” or are “out of phase”. *Id.* ¶ 20. Defendant’s complaints regarding the use of the term “substantially” in connection with these two claim terms rings hollow once the underlying technology is understood. In any case, as explained by Dr. Bikson, the term “substantially” in the context of the analysis of whether two brain waves are “in phase” or in the context of the analysis of whether two brain waves are “out of phase” is well understood and well-established in the scientific and engineering fields, such that a POSITA would readily understand the proposed construction of these claim terms. *Id.* ¶¶ 27-28.

In fact, Defendant’s complaint about the use of the term “substantially” ignores the factual reality that two brain waves are never identical (in an ideal mathematical sense) and that there is always some difference between two brain waves, regardless of how slight, which is dependent upon the level of precision of the measurement being used. *Id.* ¶¶ 33-34. Defendant’s proposed construction suffers from a similar limitation: whether two waveforms are identified as “the same” depends on the precision of the measurement. *Id.* ¶ 34. Consequently, Defendant’s proposed construction is inappropriate. It ignores the reality that two brain waves are never, in an ideal mathematical sense, exactly in phase or out of phase with one another and it interjects ambiguity into determining whether two brain waves are “in phase” or “out of phase”, where none exists in the scientific and engineering fields, by improperly suggesting that if two brain waves are not “in phase” then, by definition, they are “out of phase.”

Defendant attempts to support its proposed construction by claiming that the phrase “if any” added by Wave in connection with the claim term EEG Phase “clearly indicates that there may, *or may not*, be a difference in the timing of peaks and troughs [*sic*].” Dkt. 37 at *7 (emphasis in original). This is not true. Wave’s addition recognizes that while there are always some difference between waveforms, the difference and how it is reflected numerically depends on the precision of the measuring instrument. Bikson Dec. ¶¶ 33-34. Thus, the agreed construction of EEG Phase *is* consistent with Wave’s proposed construction, not Defendant’s. Again, Defendant provides no evidence from a POSITA or otherwise to corroborate its proposed construction or the arguments made in defense thereof.

In contrast to Defendant’s proposed use of “substantially” in connection with its claim constructions is not an attempt by Wave to improperly expand the scope of these two claim terms or introduce any uncertainty. Instead, Wave’s construction provides for use of the terms as understood by a POSITA. As such, Wave’s proposed construction of the claim terms “in phase” and “out of phase” should be adopted.

C. “Improving a physiological condition or a neuropsychiatric condition”

No.	Claim Term/Phrase and Asserted Claims Containing Term	Plaintiff’s Proposed Construction and Supporting Intrinsic Evidence	Defendant’s Proposed Construction and Supporting Intrinsic Evidence
10	[A method of] improving a physiological condition or a neuropsychiatric condition '111 Patent, Claim 1	to make or become better [the medical conditions in the claim]	Indefinite and unpatentable subject matter.

Defendant devotes most of its argument to distinguishing Wave’s cited case law and related case rather than actually analyzing the intrinsic evidence of the '111 Patent. First, Defendant claims that Wave’s “reference to its U.S. Patent No. 9,446,259 . . . is irrelevant”. Dkt. 37 at *8. However,

when convenient for Defendant, it described the '111 Patent as “independent but similar” and asserted that the '111 Patent has “teachings [that] are similar” to the other Asserted Patents, including the '737 Patent. Dkt. 34 at *1-2. The '259 Patent in the *PeakLogic* case is related to the '737 Patent asserted in this case. Tache Dec. ¶¶ 2-3. Importantly, Defendant does not dispute that the *PeakLogic* court *did* construe the claim term as proposed by Wave.

Next, Defendant attempts to distinguish Wave’s law cited in support of its contention that “[c]ourts have construed and held definite, terms of comparison like ‘improving’” Dkt. 32 at *21. Defendant does not dispute that, in these case examples, the underlying courts found the term “improving” or similar to be definite. Instead, Defendant argues that Wave “misconstrued” the cases. Dkt. 37 at *8. That is not true.

For example, in *Salix*, the Court did credit the expert’s testimony that “adequate relief” of IBS-D symptoms was definite. *See Salix Pharms., Ltd. v. Norwich Pharms., Inc.*, No. 20-430-RGA, 2022 WL 3225381, *22 (Aug. 10, 2022 D. Del.). In *Salix*, the “adequate relief” happened to be patient reported. *Id.* Here, as explained by Dr. Bikson (an opinion which has not been addressed or refuted), “‘improving’ is commonly used in psychiatric and neurological research when discussing a subject’s response to treatment and its meaning would immediately be understood by a POSITA”. Bikson Op. Dec., Dkt. 32-5 ¶ 25. Similar to Defendant’s own patents discussed below (*see infra* at *18), the '111 Patent applies to a range of physiological conditions or neuropsychiatric conditions, each “associated with a number of clinical symptoms”. Bikson Op. Dec., Dkt. 32-5 ¶¶ 25, 51. While such evaluation of whether a symptom has improved “requires a clinical assessment”, such assessment “is not subject to the whims of the researcher or physician, but is based on a comparison to known or established scientific baselines” and a POSITA would

know how to “evaluate” such symptoms. *Id.* ¶¶ 50-51. The premise of *Salix* still applies, namely that a specific numerical biomarker or comparison is not necessary for a term to be definite.

Likewise, in *Invitrogen*, the Court did not require a numerical limitation for the construction of “improving” as “generally increased”. *See Invitrogen Corp. v. Biocrest Mfg., L.P.*, 327 F.3d 1364, 1369 (Fed. Cir. 2003); Dkt. 32 at *21. The “specific metric” noted by Defendant was a baseline from which a general increase was measured. *Invitrogen*, 327 F.3d at 1369. So too here: an improvement in symptoms is measured against the starting baseline. *See also Invitrogen*, 327 F.3d at 1367 (Federal Circuit describing party’s argument as “[party] asserts that the district court erred in concluding that the preamble term ‘improved competence’ means that competence is ‘generally increased’ with no numerical limitation.”).

Lastly, in *Continental*, the Patent Trial and Appeal Board (“PTAB”) *did* note that the meaning of improved is well understood. *See Continental Ag v. Gates Corp.*, No. IPR2021-00466, 2022 WL 3012945, at *4 (P.T.A.B. July 29, 2022). This was not misconstrued by Wave as Defendant argues. *See* Dkt. 32 at *21-22 and Dkt. 37 at *10. And the specification in the ’111 Patent *does* contain “some other language of import” which helps a POSITA understand “improving”. *See* Bikson Op. Dec., Dkt. 32-5 ¶¶ 41-43, for example, noting that an autism patient showed “improvement”, specifically a “reduction of the slow waves in the patient’s EEG”, an “increase in alpha rhythm” in the brain, “frequency of seizure episodes reduced significantly” resulting in an “improvement in cognitive and motor functions”; that a pain management patient, after treatment, showed “a significant reduction in pain” and “improvement in alpha synchronization”; and that an Alzheimer’s patient showed, after treatment, “a significant improvement in short term memory and working memory”, “became more coherent”, and that her

“MMSE score improved”. While examples, they show a POSITA the types of “improve[ment]” that can be expected.

Defendant further claims that “[w]hile a precise numerical goal is not required, the patent must identify the relevant metric” Dkt. 37 at *9-10. However, Defendant cites absolutely no case law or other support for this argument. *Id.* In any case, as disclosed by Dr. Bikson, a POSITA would understand how to measure such an improvement, across a wide variety of disorders. The ’111 Patent is not required to disclose every way an “improve[ment]” can be measured to be definite or objective.

Notably, Defendant also changed its proposed claim construction without notifying Wave. On the morning of May 17, 2024, the Parties agreed to and filed an Amended Joint Claim Construction Chart. *See* Dkt. 31; Tache Dec. ¶ 4. While Defendant did modify and/or drop other claim construction arguments, it did not modify its proposed construction of a “[A method of] improving a physiological condition or a neuropsychiatric condition” as “indefinite and unpatentable subject matter”. Dkt. 34 at *6. However, mere hours later, Defendant filed its Opening Claim Construction brief, for the first time arguing that the phrase should be construed as “improving the MME score” for Alzheimer’s disease. Dkt. 34 at *5. Wave was unable to address or accurately represent the Parties arguments in its own Opening Claim Construction Brief that was filed prior to Defendant’s. *See* Dkt. 32 at *20 (stating “Defendant fails to propose any construction for this claim term”). Defendant’s intentional efforts to hide its altered claim construction argument are not well taken. *See Otsuka Pharmaceutical Co., Ltd. v. Torrent Pharmaceuticals Ltds, Inc.*, 133 F.Supp.3d 721, 728 (D.N.J. 2015) (explaining that the “Local Patent Rules ensure litigants put all their cards on the table up front”).

In any case, Defendant’s altered construction supports Wave’s argument that a POSITA would understand how to measure an improvement in a wide variety of disorders, whether by symptom improvement (self-reported or otherwise) or across a numerical metric if one is available, such as with Alzheimer’s. Tellingly, Defendant devotes almost no space (despite having 18 additional pages it could have submitted to the Court – *see* Dkt. 25 at *3) to actually discussing or distinguishing the extensive intrinsic evidence cited by Plaintiff and Dr. Bikson in Wave’s opening brief. Nevertheless, Defendant’s limited efforts (Dkt. 37 at *11-12) show that an “improvement” means any improvement.

Defendant half-heartedly addresses Wave’s other arguments, ostensibly because it cannot distinguish them. For example, Defendant argues that the “fact that the examiner did not object to this specific term . . . is irrelevant to claim construction”. Dkt. 37 at *11. Defendant cites no law or evidence in support of its contention. In fact, the law explains that “the prosecution history provides evidence of how the PTO and the inventor understood the patent”. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1317 (Fed. Cir. 2005). And whether an examiner had difficulty in applying or analyzing a term during prosecution of the patent *is* relevant to whether a claim term is indefinite. *See Sonix Tech. Co., Ltd. v. Publications Int’l, Ltd.*, 844 F.3d 1380, 1378-81 (Fed. Cir. 2017); *Niazi Licensing Corp. v. St. Jude Medical S.C., Inc.*, 30 F.4th 1339, 1347 (Fed. Cir. 2022); *Nature Simulation Sys. v. Autodesk, Inc.*, 23 F.4th 1334, 1343 (Fed. Cir. 2022).

Defendant also summarily – and without support – argues that neither dictionary definitions of improving nor Defendant’s own use of the word is relevant. Dkt. 37 at *11. However, both the dictionary definitions (which are not disputed) and Defendant’s use of the work “improving” (again, not denied) are relevant to whether a POSITA would understand the term such that it would know how to determine if a neuropsychiatric or physiological condition was

improved.⁴ *See Suffolk Techs., LLC v. AOL Inc.*, 752 F.3d 1358, 1362 (Fed. Cir. 2014); *Digital Biometrics, Inc. v. Identix, Inc.*, 149 F.3d 1335, 1344 (Fed. Cir. 1998).

Moreover, Defendant claims that its “own patents in the area do not use an ambiguous term” as “improving”. Dkt. 37 at *11. Again, Defendant’s claim is unsupported. And Defendant is wrong. Grammatical variations of the word “improving” are used in both U.S. Patent Nos. 11,786,747 (“’747 Patent”) and 11,793,456 (“’456 Patent”) cited by Defendant. *See*, for example, Tache Dec. ¶ 6 Ex. B (’456 Patent) at 5:18-35 (“Embodiments of the present disclosure are applicable to the diagnosis and treatment of all neurological or mental disease states . . . including, but not limited to . . . **improvement** of athletic performance, balance problems, and other brain disorders. . . .”) (otherwise listing more than 20 other disease states that can be treated using the technology disclosed in Defendant’s patent). *See also id.* 15:60-16:4 (similar); Tache Dec. ¶ 5 Ex. A (’747 Patent) at 7:37-54 (similar); *id.* at 20:37-53 (similar).

Lastly, Defendant now appears to admit that, if the claim term is found to be definite, Wave’s proposed construction is correct. *See* Dkt. 37 at *11 (“To be clear, the problem with this claim term is not the meaning of the term ‘improving’ as in helping a patient’s physiological and neuropsychiatric conditions to get better”). As such, the Court should adopt Wave’s proposed construction of “improving a neuropsychiatric condition or physiological condition” as “to make or become better [the medical conditions in the claim].”

IV. Conclusion

For all of the above reasons, Wave respectfully requests the Court adopt Wave’s proposed claim constructions.

⁴ Dr. Dempsey, Defendant’s expert, also understands the meaning of improved. *See* Dkt. 38-1, Bikson Resp. Dec. ¶¶ 31-36.

DATED: June 7, 2024

Respectfully submitted,

/s/ J. Rick Taché

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CERTIFICATE OF SERVICE

The undersigned hereby certifies that counsel of record who are deemed to have consented to electronic services are being served with a copy of this document via the Court's CM/ECF system per Local Rule CV-5(a) on June 7, 2024.

/s/ J. Rick Taché
J. Rick Taché